

REMARKS / ARGUMENTS

As a follow up to the Applicants' response filed on October 28, 2008, and as discussed in the telephone interviews with the Examiner that occurred on November 10, 2008 and November 26, 008, the Applicant submits herewith a declaration of Dr. Robert Shipman under 37 CFR §1.132 to provide data and other evidence in support of the non-obviousness of the claims that are currently pending in this application.

The Examiner has rejected claims 49, 50, and 78 pursuant to 35 USC §103(a) as being unpatentable over Deneffe et al. (WO02/46458) in view of Dean et al; Monahan et al; Schmitz (WO00/18912); GenBank AC069137.6; Boyd et al; GenBank U63970.1; Wan et al; Kruh et al; GenBank Z31010.1; and Ota et al. as set out on pages 5 to 9 of the Office Action dated August 7, 2008.

More specifically, the Examiner is of the opinion that it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the sequences taught in the prior art cited by the Examiner in the array taught by Deneffe et al.

First, the Examiner states that designing probes, which are equivalent to those taught in the art, is routine experimentation and that the prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as probes. The Examiner also suggests that there are many internet web sites that provide software that aid in the selection of probes, and that the prior art is "replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to design probes".

To supplement the arguments presented in the response dated October 28, 2008, the Applicant has provided, in the attached declaration under 37 CFR §1.132 of Dr. Robert Shipman, data that show that, using freely available, web-based PCR primer design software, a person skilled in the art would not be able to generate probes or sequences that

are equivalent to the ones that are claimed in the pending claims. This verifies that the claimed sequences are in no way predictable based on the teachings of the cited art in view of the knowledge of a person skilled in the art.

Further, that the Applicant's discovery of a set of nucleic acid sequences that specifically hybridize to only one of the ABC transporter genes (i.e. probes for these genes) simply cannot be characterized as the optimization of a range or other variable through routine experimentation is verified in the attached declaration where evidence is provided to show that PCR primers that were designed *in silico* to produce a single PCR product frequently generated multiple PCR products in practice. In arriving at the present invention, almost every computer-generated PCR primer set had to be modified or redesigned using the inventors' experience and knowledge to obtain a sequence that worked in practice. Further, in arriving at the present invention, there were many examples of PCR primers that produced a single PCR product that, when cloned and sequenced, was not the gene it was designed to amplify. Again, using the inventors' experience and knowledge, the primer sequences had to be modified or redesigned. There was also an occurrence where the PCR primers produced a single product that, when cloned, was lethal to the cells being transfected and transformed.

The evidence in the attached declaration supports the assertion that there is no way to predict that any given PCR product will be a functional probe for a chosen nucleic acid sequence. Using the teachings of the cited art, a person skilled in the art would not obtain products that would function as probes for the ABC transporter genes without undue experimentation and therefore would not obtain products that are equivalent with the claimed sequences. In view of this, the Applicants' submit that the subject matter of claims 49, 50 and 78 is not obvious over the cited art.

In view of the foregoing, the Applicants, again, respectfully request that the rejection to claims 49, 50 and 78 pursuant to 35 USC § 103 be withdrawn.


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Supplementary Resp. Dated January 21, 2009

Early and favorable action on the merits is awaited. Should the Examiner deem it beneficial to discuss the application in greater detail, the Examiner is invited to contact Patricia Folkins by telephone at (416) 957-1683 at the Examiner's convenience.

The Commissioner is hereby authorized to charge any deficiency in fees or credit any overpayment to our Deposit Account No. 02-2095.

Respectfully submitted,

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